

**POLITICO'S PRO HEALTH CARE BRIEFING: DRUG SAFETY AND THE TRUMP FDA
REMARKS AS PREPARED FOR TOM MORIARTY
WEDNESDAY, APRIL 5, 2017**

Good morning and welcome.

Let me start by acknowledging that today's discussion is very timely. There's tremendous interest in what role the FDA will play in the new Administration and how it may deliver a speedier approval process.

This morning, Scott Gottlieb meets with the Senate HELP committee on his appointment to be FDA Commissioner, and yesterday, the same committee held a hearing on reauthorizing user fee agreements.

So, I'm particularly glad to be here to share our perspective on the importance of having the highest functioning FDA at work in America.

ENSURING MEDICINES ARE SAFE IS OF THE UTMOST IMPORTANCE

Our ability to deliver value to the millions of patients who rely on us is contingent on the most efficient and effective FDA possible.

From the clinical trials to the patient's medicine cabinet, the private and public sectors work in tandem to ensure therapies are safe, effective and affordable.

There's ongoing discussion on how to improve and speed up the drug approval process, and as we look ahead, we're excited about the potential to optimize the process.

While drug prices are not directly in the purview of the FDA, the agency has a direct influence on market competition.

THE IMPACT OF CHRONIC DISEASE

Today, 1 in 2 Americans has a chronic illness like obesity and heart disease, and we spend nearly 85 percent of our health care dollars caring for these Americans.ⁱ

For nearly 90 percent of people with chronic and complex diseases, prescription drugs are the "first logical choice for medical intervention."ⁱⁱ

The FDA comes into play here because of its influence on the approval pipeline. By facilitating an efficient approval process, the FDA can encourage competition and innovation, which has a downstream impact on patient access and cost.

FDA'S DRUG APPROVALS BACKLOG HAMPERS COMPETITION

At the start of 2017, more than 4,000 generic drugs were pending approval at the FDA.ⁱⁱⁱ

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This is exacerbated by three factors.

First, the FDA has only been receiving user fees from generic manufacturers for a few years, as compared to brand manufacturers. As such, the approval process is still lagging.

As of July of last year, the median time for a generic to reach approval was 47 months,^{iv} compared to 10 months for the standard review of a new drug application and eight months for priority review.^v

Second, there's been a significant slowdown in receipts of generic drug applications. After reaching a high of nearly 1,500 in 2014, applications were down 43% in 2016.^{vi}

Third, more than 180 off-patent drugs are currently without generic competition.^{vii}

THE US DRUG APPROVAL LAGS BEHIND THE EU

The European Medicines Agency, Europe's version of the FDA, approves generics and biosimilar medicines much more quickly.

They have just 24 generics and biosimilars awaiting approval compared to our more than 4,000. And on average, those medicines are approved in a year.^{viii}

Biosimilars have the potential to increase patient access to more affordable versions of some of the most innovative drugs on the market. Our country is almost a decade behind.

The EU has 20 approved biosimilars,^{ix} and by comparison, the U.S. has four.^x The first biosimilar was introduced in the U.S. in 2015, in the EU it was 2006.

COMPETITION IMPROVES DRUG AFFORDABILITY

This matters because we know competition improves affordability.

At a time when the cost of prescription drugs continues to draw widespread attention, we know one of the most effective solutions is introducing competition to the market.

In 2015 alone, generic drugs saved Americans \$227 billion and more than \$1 trillion over the last decade.^{xi}

In 2016, we reduced trend, the rate of drug spending growth, from an unmanaged 11 percent to 3.2 percent actual cost growth by using our PBM management solutions.^{xii}

In fact, 38 percent of our commercial clients actually spent less on their prescription benefit in 2016 than they did in 2015.

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Importantly, out-of-pocket costs for members also dropped 3 percent compared with the previous year.

IMS data present another way to look at it. In 2015, list prices set by manufacturers rose 12.4%, whereas net prices, which account for PBM-negotiated discounts grew at just 2.8%.^{xiii}

INDUSTRY HAS SHIFTED ITS BUSINESS MODEL TO MAINTAIN PROFITS

Both the IMS data and our trend data show that increases in list prices for branded drugs continue to put upward pressure on drug spending.

This is compounded by a decrease in innovation overall. The industry is focusing less on breakthrough medicines for highly prevalent chronic disease and more on rare and orphan diseases and also on me too medicines, which are supported by high levels of direct to consumer advertising.^{xiv}

And when it comes to the success rates of new drugs reaching approval, we see much higher rates for rare conditions than for highly prevalent diseases.^{xv}

So the FDA plays a role here too by prioritizing breakthrough drug approvals and encouraging competition.

DATA AND COLLABORATION CAN HELP MAXIMIZE INNOVATION

Meaningful data and the ability to collaborate will help us maximize new innovations. Data on the efficacy and safety of new drugs are very important to health care providers tasked with appropriate prescribing.

For payers, good data makes it possible to develop evidence-based coverage decisions.

If a new drug is introduced at five times the cost of an existing treatment, strong clinical data can demonstrate that incremental benefits are significant enough to account for the increase in price or not.

We also need to develop a system that assesses the impact of drugs in the real world and solves for common barriers that limit optimal outcomes, such as a patient's adherence to medications.

For over 20 years we have known that rates of discontinuation of medication are at least three times as high in the real world as they are in highly controlled clinical trials.^{xvi}

There is great potential for public and private stakeholders to work together to improve adherence.

In order to do so, we need a regulatory environment that will allow robust collaboration among government agencies, manufacturers, PBMs and pharmacies to implement innovative adherence programs that enable the full value of a drug to be obtained.

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MAKING THE REGULATORY PROCESS MORE EFFICIENT AND INCREASING COMPETITION

At the end of the day, we all want to make sure we have access to safe, effective and affordable drugs

A good place to start is by speeding approval of generic drug applications. And because not all new generic entrants will impact competition to the same degree, the FDA should prioritize first generics when there's no competition for an indication and second generics that are known to significantly lower prices.

The FDA can attract additional entrants into the market by providing incentives, such as expedited review for drugs with only one manufacturer.

We also need to increase the availability of biosimilars. I'm sure we'll hear some ideas on how to do this during today's discussion.

CONSIDERATIONS AS THE DEBATE MOVES FORWARD

As the debate continues over how to shape the future of the FDA, the agency's role in ensuring our medicines are safe and effective must remain paramount.

At the same time, we must also remember its impact on competition, access and ultimately affordability.

Thank you for your time this morning. I'll turn it over to Joanne to get the panel discussion underway.

ⁱ Centers for Disease Control. Chronic Disease Overview. Retrieved from <https://www.cdc.gov/chronicdisease/overview/>

ⁱⁱ Orszag, J., & Green, K. (2011, December 5). The Economic Benefits of Pharmacy Benefit Managers. Retrieved from <https://www.sec.gov/Archives/edgar/data/1170650/000095012311101989/y93719exv99w2.htm>

ⁱⁱⁱ U.S. Food & Drug Administration. (2017, January 1). Generic Drug Review Dashboard Report. Retrieved from <https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/ucm484609.htm>

^{iv} Association for Accessible Medicines as reported in Kaiser Health News. (2016, September 6). EpiPen Controversy Fuels Concerns Over Generic Drug Approval Backlog. Retrieved from <http://khn.org/news/epipen-controversy-fuels-concerns-over-generic-drug-approval-backlog/>

^v U.S. Food & Drug Administration. (2016, December 31). CDER Approval Times for Priority and Standard NDAs and BLAs. Retrieved from <https://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/DrugandBiologicApprovalReports/NDAandBLAApprovalReports/UCM540942.pdf>

^{vi} Woodcock, J. (2017, March 2). Testimony before the United States House of Representatives Committee on Energy and Commerce Subcommittee on Health.

^{vii} Ibid.

^{viii} Lupkin, S. Kaiser Health News. (2016, September 6). EpiPen Controversy Fuels Concerns Over Generic Drug Approval Backlog. Retrieved from <http://khn.org/news/epipen-controversy-fuels-concerns-over-generic-drug-approval-backlog/>

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^{ix} QuintilesIMS. Biosimilars by Region: Europe. Retrieved from <http://www.quintiles.com/microsites/biosimilars-knowledge-connect/biosimilars-by-region/europe>

^x Minaya, E. Wall Street Journal. (2016, September 23). FDA Approves Amgen's Biosimilar Version of Humira. Retrieved from <https://www.wsj.com/articles/fda-approves-amgens-biosimilar-version-of-humira-1474669560>

^{xi} Association for Affordable Medicines. (2016, October 19). Generic Drugs Continue to Deliver Billions in Savings to the U.S. Health Care System. Retrieved from <http://www.gphaonline.org/gpha-media/press/generic-drugs-continue-to-deliver-billions-in-savings-to-the-u-s-healthcare-system-new-report-finds>

^{xii} CVS Health Insights Executive Briefing. (2017, March 15) Trend Drops to the Lowest Level in Four Years. Retrieved from <https://cvshealth.com/sites/default/files/cvs-health-trend-drops-to-the-lowest-level-in-four-years.pdf>

^{xiii} QuintilesIMS. (2016, April 14). Medicines Use and Spending in the U.S. – A Review of 2015 and Outlook to 2020. Retrieved from <http://www.imshealth.com/en/thought-leadership/quintilesims-institute/reports/medicines-use-and-spending-in-the-us-a-review-of-2015-and-outlook-to-2020>

^{xiv} Nielsen and Kantar Media

^{xv} BIO. (2016). Clinical Development Success Rates: 2006-2015. Retrieved from <https://www.bio.org/sites/default/files/Clinical%20Development%20Success%20Rates%202006-2015%20-%20BIO,%20Biomedtracker,%20Amplion%202016.pdf>

^{xvi} Andrade, S., Walker, A., Gottlieb, L. Et Al. New England Journal of Medicine. (1995). Discontinuation of Antihyperlipidemic Drugs — Do Rates Reported in Clinical Trials Reflect Rates in Primary Care Settings?